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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,221	10/20/2003	Georg Berger	3975.025	4078

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EXAMINER

ARNOLD, ERNST V

ART UNIT PAPER NUMBER

1616

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/689,221

Applicant(s)

BERGER ET AL.

Examiner

Ernst V. Arnold

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-21 are pending in the application. Claims 14-21 have been withdrawn as being directed to non-elected subject matter.

The Examiner acknowledges Applicant's response to the Office Action filed on 7/10/06. Applicant respectfully traverses the restriction requirement on the grounds that the Examiner ignored the presence of the amorphous phase (c). Applicant asserted that it seems impossible to use a powder mixture for a biocement of the invention with diphosphates according to the process mentioned by the Examiner. The Examiner does not agree. The Examiner maintains that it is reasonable to have an amorphous phase with the method as previously suggested by the Examiner. The Examiner also notes for Applicant that in the finding of allowable subject matter there will be rejoinder of the process claims commensurate in scope with the allowable claims. The restriction is maintained.

Again Applicant is advised of the use of proper Markush language in instant claim 2, which has "selected from among" instead of ---selected from the group consisting of---.

Withdrawn rejections:

Claims 1-13 were rejected under 35 U.S.C. 112, first paragraph. Applicant has amended claim 1 to recite specific materials in specific ranges. The Examiner withdraws the rejection.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 19744809 C1 in view of Gross et al. (US 4,239,113) and Broemer et al. (US 3,922,155) and Constantz et al. (US 6,002,065).

The Abstract of DE 19744809 C1 discloses a porous rapidly soluble glass ceramic comprising $\text{Ca}_2\text{KNa}(\text{PO}_4)_2$, $\text{Ca}_5\text{Na}_2(\text{PO}_4)_2$ or $\text{Ca}_6\text{Na}_3(\text{PO}_4)_5$ as the main crystal phase which is useful as a resorbable bone substitute, a substrate for drugs (e.g., antibiotics), proteins, enzymes or cells or a filter aid. Claim 7 of DE 19744809 C1 clearly claims a composition comprising (wt%):

30-50	P_2O_5
20-55	CaO
5-25	Na_2O
0.01-20	K_2O
0-15	MgO
0-10	SiO_2

The composition reads upon instant claim 7. It is the Examiner's position that heat melting these materials will intrinsically form the instantly claimed phosphate mixtures in instant claim 1 including an amorphous phase, which makes up 0.1 to 65% by weight and 0.1-15% by weight chain phosphates. In addition, since magnesium is

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present in the composition, then it is reasonable to assert that mixed crystals would intrinsically form in the ceramic material.

I. The Abstract of DE 19744809 C1 does not expressly disclose the powder mixture with 40-99% by volume of powder having a particle size of 0.1-10 μm ; 1-20% by volume of a powder having a particle size of 10-43 μm ; 0-59% by volume of having a particle size of 43-315 μm .

II. The Abstract of DE 19744809 C1 does not expressly disclose the addition of alpha- or beta-tricalcium phosphate to the powder mixture.

III. The Abstract of DE 19744809 C1 does not expressly disclose the powder mixture in the form of an aqueous solution, a suspension or a paste.

IV. The Abstract of DE 19744809 C1 does not expressly disclose a two component kit wherein one component is the powder and the other component is made up of a water phase.

I. Gross et al. teach a composition for the preparation of a bone cement wherein the bioactive glass ceramic powder has a particle size of 10-200 micrometers. The glass ceramic powder is the same as that disclosed in US 3,922,155.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use ceramic powders of 10-200 micrometer particle size as a bone cement.

One of ordinary skill in the art would have been motivated to do this because Gross et al. teach that such cements have advantageous processing characteristics,

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good mechanical properties and characteristics favorable to the development of bone structure (Column 2, lines 10-16).

II. Broemer et al. teach a glass ceramic material comprising SiO_2 , P_2O_5 , Na_2O , K_2O , MgO and CaO useful as bone and tooth replacement material (Abstract). Broemer et al. teach that calcium orthophosphate, $\text{Ca}_3(\text{PO}_4)_2$, otherwise known as tri-calcium phosphate or tertiary calcium phosphate, can be added to the composition at about 10 to about 30 percent by weight (Column 4, lines 1-2, column 5, Table 1 and claim 1). Broemer et al. discloses the leaching out of a preferred glass ceramic material with Ringer's solution in Figure 1 (Column 5, lines 1-2).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add tricalcium phosphate to the composition of DE 19744809 C1 as suggested by Broemer et al. for the purpose of making a biocompatible bone cement and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Broemer et al. report that the composition has the advantages of biocompatibility and the materials can be worked mechanically to form molds (Column 9, lines 64-column 10, lines 1-22).

III and IV. Constantz et al. teach calcium phosphate cement compositions and kits for preparing a calcium phosphate mineral for use in bone defects and dental applications (Abstract; column 2, lines 46-55; and claims 1-10). Constantz et al. teach the mixing of solutions of the cement in order to measure the setting time (Column 10, Example 3, for example). Constantz et al. teach a kit for preparing a calcium phosphate

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mineral wherein the dry ingredients and the aqueous solution are present in separate containers (Claims 1, 4 and 8). The Examiner interprets this to read upon a 2-compartment kit.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the powder mixture in the form of a aqueous solution, a suspension or a paste.

One of ordinary skill in the art would have been motivated to do this because it would have been routine to mix the powder in a solution and measure the amount of time it took for the cement to cure after application; an important piece of information for the orthopedic surgeon applying the bone cement to a patient.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to put the composition of DE 19744809 C1 in a kit as suggested by Constantz et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because a kit would enhance the ease of use of the composition for the practitioner applying the cement and would enhance the marketing value of the product.

The relative amount of orthophosphates, 40-95% or 50-90% by weight, and diphosphates, 1 to 22% or 5-22% by weight, is deemed merely a matter of routine optimization of standard working conditions, which is well within the purview of one of ordinary skill in the art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

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invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Response to arguments:

Applicant asserted that the product of Berger is different from the product of the instant invention because; "The product prepared is completely different from the instant product with respect to the crystal phases." It is the Examiner's position that Berger uses the same materials in the same amounts and subjects them to a melting process. The Examiner notes that only 0.1% by weight of the composition has to be a substance selected from the group consisting of $\text{Na}_2\text{CaP}_2\text{O}_7$, $\text{K}_2\text{CaP}_2\text{O}_7$, $\text{Ca}_2\text{P}_2\text{O}_7$, NaPO_3 and KPO_3 (instant claim 1). Since Berger discloses the same starting materials in the same amounts, then it seems reasonable to the Examiner, without evidence to the contrary, that the method of Berger would produce one or more of those components in the composition. Simply because Berger didn't disclose the presence of any diphosphates doesn't mean that they were not present. The comprising language of the instant claim 1 does not preclude the presence of the crystals disclosed by Berger.

Applicant asserted that the references of Gross et al. and Broemer et al. are directed towards glass ceramics and bone cements, which contain SiO_2 thus making the products not resorbable. Therefore there is no motivation to combine the references. The Examiner cannot agree. The art teaches compositions for bone cements, DE 19744809 C1, the particle size for bone cements, Gross et al., the addition of known

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materials useful in bone cements, Broemer et al. and finally Constantz et al. for making a kit comprising bone cement materials. The primary reference teaches the composition while the secondary references provide teachings for one of ordinary skill in the art to optimize the composition.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

I. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 of copending Application No. 10/689,219 in view of Gross et al. (US 4,239,113). The copending application teaches the same ³¹P-NMR and X-ray diffractometric measurements to identify the composition with overlapping ranges of orthophosphate, diphosphate and amorphous components.

One of ordinary skill in the art would have recognized the obvious variation of the instant application over the copending application because Gross et al. teaches the use of particles from 10-200 microns in size for bone cement compositions.

This is a provisional obviousness-type double patenting rejection.

Response to arguments:

Applicant did not present any arguments as to why instant claim 1 is not obvious over claim 1 of copending Application No. 10/689,219 in view of Gross et al. (US 4,239,113) and the rejection is maintained.

II. Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 4, 7-9, 17 and 21 of copending Application No. 10/689,217 in view of Gross et al. (US 4,239,113). The copending application teaches the same ³¹P-NMR and X-ray diffractometric measurements to identify the composition with overlapping ranges of orthophosphate, diphosphate and amorphous components in claims 1 and 2. The amounts of chain phosphates in the composition as well as orthophosphates and diphosphates is fairly disclosed by 10/689,217 in claims 4 and 7-9. One of ordinary skill in the art would have recognized the obvious variation of the instant application over the copending application because Gross et al. teaches the use of particles from 10-200 microns in size for bone cement compositions. The materials in claim 17 and the method disclosed in claim 21 renders the product by process of instant claim 1 obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection.

Response to arguments:

Applicant asserted that amended claim 1 clearly distinguishes the instant invention from the invention in copending Application No. 10/689,217 in view of Gross et al. (US 4,239,113). However the Examiner notes that the instant amended limitations are recited in claim 2 of the copending application. How can the powder mixtures for resorbable calcium phosphate biocements/bone replacement material be different if they have the same components and the same ³¹P-NMR measurements and the same X-ray diffractometric measurements? The rejection is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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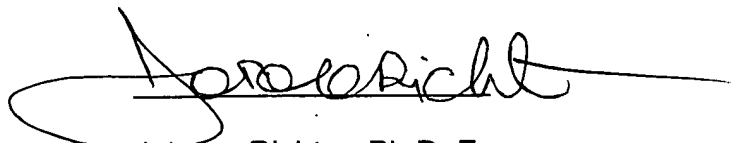
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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